**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF VIRGINIA**
ALEXANDRIA DIVISION

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| TRACELINK, INC.<br>Plaintiff,<br><br>vs.<br><br>HEALTHCARE DISTRIBUTION ALLIANCE,<br><br>Defendant. | Civil Action No. _____<br><br>COMPLAINT<br><br>**DEMAND FOR JURY TRIAL** |

Plaintiff TraceLink, Inc. ("TraceLink"), through its undersigned attorneys—upon knowledge with respect to its own acts and those it witnessed first-hand, and upon information and belief with respect to all other matters—hereby alleges against Defendant Healthcare Distribution Alliance ("HDA"):

## NATURE OF THE ACTION

1. This case concerns an antitrust conspiracy engaged in by and through the Healthcare Distribution Alliance, an association of wholesaler distributors of pharmaceutical products, and its controlling members – including Cardinal Health, AmerisourceBergen and McKesson Corporation. Specifically, the HDA coordinated and, served as a conduit for, collective, anticompetitive acts designed to foreclose, and that have had the effect of substantially foreclosing, competition in the supply of products that "track and trace" pharmaceuticals as they flow through the supply chain, including competition from plaintiff TraceLink. These products, among other things, enable compliance with the Drug Supply Chain Security Act of 2013 ("DSCSA").

2. The HDA's ostensible purpose is to act as a trade association that (1) provides a forum for its members to discuss topics relevant to the wholesale distribution market and (2)

advocates on policy and legislative initiatives on behalf of its distributor and wholesaler members. However, beginning in July 2017, the HDA ventured into the commercial arena, supplying, on behalf of its collective membership, a track and trace compliance solution called "Origin."

3. The HDA sought to develop Origin after certain of its members, in a confidential TraceLink briefing, learned of TraceLink plans to supply a track and trace product that would assist companies in the healthcare industry to comply with DSCSA regulations. These members reported to the HDA, and, as a result, to other HDA member wholesaler competitors about the TraceLink product functionality and TraceLink strategies. The HDA then, informed by these product designs and with the assistance of another technology vendor called ValueCentric, chose, collectively with and on behalf of its members, to supply and market its own DSCSA-compliant solution.

4. The HDA has used its "association" status to coerce or persuade its members to use Origin and, in turn, to not use the track and trace products offered by private competitors, including plaintiff TraceLink. Moreover, as part of its anticompetitive scheme, the HDA has used exclusionary license contracts to prevent customers (many of whom have been forced to use Origin) from using competitive track and trace compliance products, such as that supplied by TraceLink, to access critical, pharmaceutical company data that resides in the Origin database. Had the HDA permitted open standards for the exchange of this master data – as it had promoted open standards in other contexts – rather than imposed exclusionary licenses upon customers, competition in the relevant track and trace compliance product market would have flourished. By forcing a closed system upon the industry, HDA, as described more fully herein, has raised costs for customers that, but for the coercive and conspiratorial acts of HDA and certain

powerful HDA members, would have been willing to use rival track and trace technology supplied by competitors.

5. To further the goals of this conspiracy, HDA members, including members of its Board of Directors and Executive Committee – who collectively account for the distribution of over 80% of all drugs sold in the United States and who have a pecuniary interest in the success of Origin – have used their collective and substantial market power to force their suppliers (such as pharmaceutical companies) and trading partners (such as pharmacies) to use Origin. The clients of these entities have no effective choice but to accede to this forcing and forego using competitive track and trace products, such as that offered by TraceLink.

6. The HDA and its co-conspirators, through their collective efforts, conspired to unreasonably restrain trade and monopolize markets for track and trace technology. Through this conspiracy, they have caused and/or will cause substantial anticompetitive effects. Among other things, their conspiratorial conduct has, to date, foreclosed competitors that develop and offer products superior in quality from competing on the merits. It also has led or will lead to customers paying supra-competitive prices for track and trace technology. And it will stunt continued innovations that otherwise would have been made in this technology.

7. There is no legitimate business purpose or procompetitive benefit that offsets the anticompetitive impacts caused by the scheme engaged in by the HDA and its members. Unlike valid standard setting organizations, HDA has neither developed Origin through an open due process, nor sought to craft a non-discriminatory protocol that can be utilized by all vendors. To the contrary, by acting as the supplier of Origin, it has acted merely to reap monies for itself and its wholesaler and distributor members.

8. TraceLink has incurred substantial damages in the form of lost profits by virtue of the anticompetitive acts detailed here.

9. Accordingly, TraceLink brings this action under Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2), under the Virginia Antitrust Act (Va. Code § 59.1-9.1 *et seq.*), and state laws against tortious interference with contract and tortious interference with prospective business relations. It seeks treble damages and an injunction precluding the HDA and its co-conspirators from continuing to engage in their conspiratorial, anticompetitive acts.

## PARTIES

10. Plaintiff TraceLink, Inc. is a closely-held corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 400 Riverpark Drive Suite 200, North Reading, MA 01864. TraceLink offers a track-and-trace network for connecting the life sciences supply chain and has been in business since 2009.

11. Defendant Healthcare Distribution Alliance is an industry trade association that is supposed to be a "not for profit" entity, with its principal place of business located at 901 North Glebe Rd. Suite 1000, Arlington, VA 22203. HDA serves as a vehicle for its members to act collectively and represents the interests of wholesaler distributors in the life sciences supply chain. The operations and actions of HDA are controlled by a Board of Directors and Executive Committee upon which HDA wholesaler distributor members sit. The HDA's "mission statement" states that it exists to "influence standards and business processes that produce efficient health care commerce." It does not state that HDA intended to serve as a commercial supplier of any type of product for its members.

## CO-CONSPIRATORS

12. Various other persons, firms and corporations, not named as defendants, have participated as co-conspirators with HDA and have performed acts and made statements in furtherance of the conspiracy. Such co-conspirators specifically include, but are not limited to, wholesaler distributors AmerisourceBergen, Inc., McKesson Corporation, Inc., and Cardinal Health, Inc. (together, the "Big Three").

13. The HDA is dominated by the Big Three, which substantially control its operations. Executives of each of the Big Three sit on the HDA Board of Directors and Executive Committee.

14. AmerisourceBergen Corporation, Inc. is a public corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087. AmerisourceBergen is one of the largest global pharmaceutical sourcing and distribution services companies. According to the Form 10-K that AmerisourceBergen filed with the Securities and Exchange Commission for fiscal year 2016, AmerisourceBergen earned $146.84 billion in revenue and $1.42 billion in profit in that fiscal year.

15. McKesson Corporation, Inc. is a public corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at One Post Street, San Francisco, CA 94104. McKesson is one of the largest global pharmaceutical sourcing and distribution services companies. According to the Form 10-K that McKesson filed with the Securities and Exchange Commission for fiscal year 2016, McKesson earned $198.53 billion in revenue and $5.15 billion in profit in that fiscal year.

16. Cardinal Health, Inc. is a public corporation organized and existing under the laws of Ohio, with its principal place of business located at 7000 Cardinal Place, Dublin, Ohio 43017.

Cardinal Health is one of the largest global pharmaceutical sourcing and distribution services companies. According to the Form 10-K that Cardinal filed with the Securities and Exchange Commission for fiscal year 2016, Cardinal earned $129.98 billion in revenue and $1.28 billion in profit in that fiscal year.

17. Co-conspirators also include wholesaler distributors that are members of HDA, other than the Big Three, that stand to benefit from the foreclosure of competing track-and-trace compliance providers or possessors of supply chain data. Such co-conspirators aided, abetted, or participated with the HDA in the commission of the wrongful acts alleged in this Complaint.

## JURISDICTION AND VENUE

18. TraceLink brings this action, in part, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, for Defendant's violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1337.

20. TraceLink also brings this action under state law for violation of the Virginia Antitrust Act, tortious interference with contract, and tortious interference with prospective business relations. This Court has supplemental subject matter jurisdiction over these state law claims pursuant to 28 U.S.C. § 1367.

21. This Court has personal jurisdiction over Defendant and venue is proper in the Eastern District of Virginia pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391 because the Defendant is a resident of this District.

22. Defendant HDA and its co-conspirators are engaged in activities, including those that form the basis of this Complaint, that substantially affect interstate trade and commerce.

## FACTUAL BACKGROUND

### A. The Life Sciences Industry and Supply Chain

23. The life sciences industry is a dynamic and important segment of the American economy. Prescription drugs have become an essential element of modern health care. Today, an individual can fill most prescriptions almost immediately, as there is a pharmacy in nearly every neighborhood in the United States. Most pharmacies and other dispensers, like hospitals, can fill most prescriptions on the spot, or at least guarantee next day delivery. The ease with which people can obtain their prescription drugs requires an entire supply chain capable of delivering the correct drugs in the correct dosages from manufacturers to local dispensers. This supply chain includes manufacturers who produce the drugs, wholesaler distributors who distribute the drugs, as well as dispensers, repackagers, and logistics providers.

24. It is challenging to distribute and deliver prescription drugs from manufacturers to dispensers. It involves not only the quick and efficient transportation of drugs on a daily basis, but also large facilities to stock a constant inventory of thousands of different brands of drugs. Most dispensers, including neighborhood independent pharmacies, chain pharmacies, hospitals, nursing homes, and alternative care sites, lack the capacity to store the large number and variety of drugs that they sell. To fill prescriptions on the spot every day, dispensers must be able to obtain the requested drugs on a continuous basis from the manufacturers as quickly as possible. Thus, the fast and efficient distribution of prescription drugs is a critical component of the pharmaceutical industry.

25. Wholesaler distributors – such as AmerisourceBergen, Cardinal, and McKesson – are the middle men between manufacturers and dispensers. They provide an expeditious and cost-effective means for the purchase, delivery, and sale of prescription pharmaceuticals. They

purchase and obtain drugs from the manufacturers, store the drugs in anticipation of customer demand, and then sell and deliver the desired quantities to the individual dispenser.

**B. The Drug Supply Chain Security Act**

26. In today's life sciences supply chain, illicit activity thrives. The counterfeit drug market generates $75 billion annually and kills tens of thousands of people each year. More than forty (40) countries have responded with new laws that will, by 2019, regulate 75% of the world's prescription medications as they travel through the supply chain.

27. In response to growing concerns about this illicit activity, Congress enacted the Drug Supply Chain Security Act ("DSCSA") to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain in the United States. The DSCSA improves product integrity by calling for the documenting of each change of ownership of pharmaceutical products in the supply chain. The DSCSA, moreover, outlines steps to build an electronic, interoperable system to identify and follow ("track and trace") these drugs from manufacturer to dispenser. Pursuant to these ends, the DSCSA specifically directs the FDA under the clause for "Standards for Interoperable Data Exchange" to work with industry players to craft standards to support a secure and interoperable electronic data exchange among those in the pharmaceutical distribution chain.

28. The DSCSA establishes new processes for identifying suspect and illegitimate products in the supply chain, allowing supply chain trading partners to more quickly identify, quarantine, and investigate suspect products. It also enhances the process for manufacturers, distributors, and others to notify the FDA of the existence of potentially dangerous products in the supply.

29. As a result of the DSCSA, entities in the life science supply chain now have and will have access to substantially more information about the flow of a particular product across transactions. The DSCSA envisions the development of an electronic capability that would enable a member of the pharmaceutical supply chain to receive transaction information about a drug that it purchased. It also envisions that this capability will allow the FDA or other authorized parties to construct a full transaction history for specific pharmaceutical products down to the individual sales package level.

30. The DSCSA outlines critical steps to create an interoperable electronic track and trace system within ten years from enactment. In accordance with the DSCSA outline, the FDA published standards and industry guidance to promote the development of technologies for the interoperable exchange of information for the tracing of certain prescription drugs. At the heart of these efforts are standardized product data descriptions, known as the "GTIN," and open standards for information exchange.

31. The FDA is implementing the DSCSA in several phases. Starting on January 1, 2015, the FDA required that manufacturers, wholesalers, and repackagers exchange track-and-trace data at the manufactured batch level (the "lot level") of identification. This information includes what is called the "transaction information," the "transaction history," and "transaction statements" at the lot level. The FDA required dispensers to exchange this information as of July 1, 2015.

32. Between 2017-2020, pharmaceutical drug products must be "serialized." Specifically, they must include unique identification at the saleable unit level (rather than merely at the lot level); and participants in the supply chain must ensure that they transact with only

serialized drug products. Serialization is thus significantly more individualized for each purchased product than lot-level identification.

33. Per the DSCSA, serialization data, known under DSCSA as a "product identifier," will be printed on all pharmaceutical products in a machine-readable bar code, as well as in human readable formats. In the example shown below, the product identifier includes four data elements: (1) A unique "GTIN" number that embeds the National Drug Code, a universal product identifier for human drugs in the United States; (2) the serial number for the specific product unit; (3) the lot number, which identifies the larger batch that product came from; and (4) the product expiration date. The serialization information is located on the outside of the box


so that businesses in the supply chain, including distributors, re-packagers, and dispensers can quickly review the serialization data.

34. Those businesses then compare the serialization information on the product package to information in a track-and-trace database, such as Origin or TraceLink. Track-and-trace compliance solutions, like Origin and TraceLink, receive serialization information from prior owners of the product in the supply chain (e.g., product manufacturer or wholesaler distributor). Thus, if there is a match between the product's actual serialization information and information in the track-and-trace database, then the business knows that the product that it received has met the DSCSA's requirements for product integrity.

35. While serialization and barcoding regulations have helped to ensure product integrity, they have also created a complex, strategic data management challenge. Serialization involves more than merely putting a number on a bottle or package. The data generated from transaction events are orders of magnitude beyond what companies in the life sciences supply chain have ordinarily maintained. Moreover, trade partners in the supply chain must manage the flow of this data across a wide variety of networks, including internally within a company, among supply chain partners, and with the government. Shortages, damaged product, broken serials, and other exceptions to perfect serialization create logistical headaches that obstruct commerce in pharmaceuticals, particularly when stretched over millions of transactions. Additionally, many trade partners have particular data preferences that must be taken into account. Because of the complexity of serialization data and the many different systems that utilize it, it is of paramount importance that this data be maintained and transferred correctly and carefully.

**C. TraceLink – a Market Innovator**

36. TraceLink provides track and trace solutions to life sciences supply chain companies, including pharmaceutical businesses, wholesaler distributors, contract manufacturers

and packagers, third-party logistics companies, hospitals, pharmacies, and other dispensing entities. TraceLink's core innovations use interoperability across standards to optimize the exchange of standardized drug product information, even among competing products.

37. TraceLink's main product is the Life Sciences Cloud, which has quickly become a significant pharmaceutical track-and-trace network. TraceLink's platform is purpose-built for serialization and enables a whole new dimension of collaboration, transforming the way that supply chain companies interoperate while seamlessly maintaining compliance.

38. The Life Sciences Cloud allows any company in the life sciences supply chain to connect with all of their domestic and worldwide trading partners. TraceLink provides tailor-made compliance solutions for track and trace regulatory requirements set not only by the United States, but by countries around the world, including China, Brazil, India, South Korea, the European Union, and more.

39. Through its anticompetitive conduct, the HDA is depriving and will deprive a substantial number of companies from accessing the unique and substantial benefits of TraceLink's Life Sciences Cloud, including track-and-trace compliance—not just in the United States, but globally—and an easy-to-use compliance system architecture.

### D. HDA Develops Origin As A Proprietary Product, Mandates its Use, and Excludes TraceLink.

40. Occasionally in the past, the HDA has convened working groups (made up of various HDA member executives) to develop guidelines to help the industry standardize policies, procedures, or data exchange methods that are to be used by HDA members and their trading partners. These guidelines generally have been developed through processes controlled by the HDA and the Big Three. One of the workgroups that the HDA formed to develop these standard

policies, procedures and data exchange methods is called the "Traceability Workgroup." Each of the Big Three sits on the Traceability Workgroup.

41. The HDA developed these standard policies, procedures or data exchange methods at the initiative of, and to primarily advance strategies defined by, the Big Three. Nonetheless, these past efforts permitted, at least, a degree of competition among technology providers to develop products that met these standard policies, processes or methods of data exchange.

42. An example of the HDA-controlled process for developing standards occurred in 2014. Then, the HDA's Traceability Workgroup developed what became the "HDMI Electronic Data Interchange (EDI) Guidelines for the 856 Advance Ship Notice to Support Implementation of DSCSA" (the "EDI Guidelines"). EDI was a broadly adopted, multi-industry set of electronic data interchange standards to support the exchange of information for, among other things, purchase orders and delivery notices. After the Traceability Workgroup drafted an initial set of EDI Guidelines, they were then circulated to the entire HDA wholesaler distributor membership for feedback and revision. In response to concerns raised about the EDI Guidelines provided by HDA membership, the HDA revised them and then published them. After publication, the HDA circulated those Guidelines to all members in order to raise awareness of the data exchange standards.

43. The HDA did not require its membership, or their trade partners, to utilize the EDI Guidelines. Rather, the HDA circulated those voluntary Guidelines to facilitate uniformity within the life sciences supply chain.

44. In contrast to those previous processes, the HDA, with the assistance of its Traceability Workgroup, adopted a wholly closed and exclusionary process to develop the Origin

product. It developed, in secret, a Request for Proposal (the "RFP") for the creation of a data repository and exchange product that eventually became known as Origin. The HDA did not issue the RFP broadly to solicit responses from all potential companies qualified to develop and manage the product and services in order to assure that its members were provided with the highest quality solution. Instead, the HDA, and its largest members, made the collective decision to exclude TraceLink from this process. This process was not the product of unilateral action, but rather was a process that was driven by the collective efforts of those entities that sat on the Traceability Workgroup. Moreover, this process was discriminatory and violated the due processes required in adopting and promulgating fair and objective industry standards. Further, the process was contrary to the goal of obtaining competitive bidding proposals from highly qualified candidates.

45. This process was particularly discriminatory because the HDA and members of the Traceability Workshop knew that TraceLink had a specialized expertise that uniquely qualified it to compete in the RFP. TraceLink presented a confidential plan to develop a product with certain similarities to Origin at least twice to several members of the HDA before the HDA embarked on the development process. TraceLink gave the first presentation on June 24, 2015 during a confidential workshop that TraceLink held for customers about the DSCSA's requirements, noting how TraceLink's product facilitates compliance with these requirements. TraceLink gave a second confidential presentation on March 15, 2016, during a customer strategic review meeting held at TraceLink, in which TraceLink explicitly discussed what became Life Sciences Cloud – its track and trace, shared network master data product. The HDA learned of TraceLink's plans through HDA members who sit on HDA committees including the Traceability Workgroup.

46. The members of the HDA Traceability Workgroup, including the Big Three, selected ValueCentric, LLC ("ValueCentric") as HDA's vendor to develop Origin. Rather than create an open product for data exchange and a commonly available repository that could be utilized by all service providers, the HDA developed Origin as a *proprietary* solution that HDA would supply and market.

47. Despite their similarities, Origin and the TraceLink Life Sciences Cloud differ in two major respects. First, TraceLink's product is based on an interoperable open standards approach that promotes marketplace competition while facilitating efficient customer exchange of crucial product data with their trade partners. By contrast, Origin is based on a closed proprietary platform that excludes market competition.

48. Second, Origin has much less functionality as a track and trace product. It is solely a data repository that identifies specific packages of drugs that have been put into the supply chain. To the contrary, the Life Sciences Cloud provides the user not only with this information, but also with information regarding, among other things, when and to whom the product was sold. Moreover, the Origin repository, unlike the Life Sciences Cloud, relies substantially on US-based technical nomenclature and product master data, and thus lacks the flexibility to be used in international transactions. As a result, Origin currently has substantially less utility than TraceLink's solution, and excludes rather than promotes market competition and innovation for crucial track and trace solutions.

49. Despite the superiority of the TraceLink track and trace product, the HDA urged its wholesaler distributor members to mandate that their business partners use only the Origin product. The HDA made this request at least once, at a conference in early 2017. The HDA wholesaler distributor members have, in turn, mandated that their business partners use the

Origin product in their dealings. These mandates have effectively forced customers of wholesaler distributors with substantial market power, like the Big Three, to use Origin rather than TraceLink or another competitive DSCSA track-and-trace compliance solution.

50. In addition, the HDA, as the contracting party supplying Origin and with the approval of its members, requires that Origin users and contributors accept sweeping, restrictive, non-compete clauses as a condition to access and use the Origin database. For example, the HDA User Agreement [§ 5(g) and (h)] and Contributor Agreement [§ 8(f) and (g)] for Origin contain restrictions that prevent licensees from providing track and trace product data from Origin's GTIN database to third-parties – even though HDA creates none of the data in the Origin database. Contributors create virtually all the data and merely deposit that data in Origin. The non-compete clauses also prohibit competitors from accessing that data for pharmaceutical manufacturers and distributors that own or have the right and need to use the GTIN data. These clauses, which in the very least require users of competitive track and trace solutions to incur substantial opportunity costs by forcing them to re-enter their data into the competitive systems, effectively prohibit manufacturers and distributors from dealing with competitors, like TraceLink.

51. These non-compete clauses curtail innovation and competition by service providers and directly conflict with the DSCSA's interoperability goals. Moreover, the HDA has used these contract clauses to effectively assert exclusive ownership over standardized product data in Origin – data supplied by manufacturers that HDA neither created nor defined. As a result, competitors have been prohibited from accessing the Origin database to obtain that standardized data, and cannot use that data to provide interoperable track and trace solutions.

52. A particular compliance solution becomes more valuable to life science supply chain businesses as more of its business partners use that product. As more supply chain partners are forced to use Origin, they will find it more costly to switch to a competing compliance solution that does not have as many users. These clauses, which preclude seamless data transfers from the collectively-supplied Origin product to those offered by competitors such as TraceLink, are particularly harmful to TraceLink's business by creating substantial disincentives for purchasers of DSCSA compliance solutions to purchase a non-Origin product.

53. There is no legitimate business interest that would require that HDA impose these clauses.

**E. The HDA's Conduct Will Irreparably Harm TraceLink.**

54. In addition to the financial damages caused already, the HDA's conduct has and will continue to cause irreparable harm to TraceLink. TraceLink had announced support for an open standards-based approach to master data exchange, and had won support from many current customers. In light of the conspiracy to mandate the use of Origin and HDA's exclusionary licenses, a number of TraceLink's customers have discontinued their subscription to TraceLink's Life Sciences Cloud to date, with an unknown number of them switching directly to the HDA's competing solution. If the HDA continues its illegal conduct as it has threatened, then TraceLink will likely lose the ability to market its competing master data, track and trace modules to the pharmaceutical supply chain, as the network effects of the Origin non-compete clauses will make using TraceLink's product unviable.

55. The impact of the HDA's conduct will be detrimental to TraceLink if the HDA's conduct is not immediately halted and corrected.

## ANTITRUST ALLEGATIONS

56. The HDA and its co-conspirators combined, conspired, and engaged in a concerted effort to unreasonably restrain trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, *et seq.*, and in violation of the Virginia Antitrust Act, Va. Code § 59.1-9.5, to eliminate TraceLink and other DSCSA track-and-trace compliance solution providers as competitors in the relevant markets.

57. The HDA and its co-conspirators have unlawfully, and with specific intent, conspired to monopolize the relevant markets, and have unlawfully effectuated this conspiracy to monopolize by overt exclusionary acts, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, *et seq.*, and in violation of the Virginia Antitrust Act, Va. Code § 59.1-9.6, to eliminate TraceLink and other DSCSA track-and-trace compliance solution providers as competitors in the relevant markets

**A. Interstate Commerce**

58. The development, marketing, and sale of DSCSA track-and-trace compliance solutions are in, and affect, interstate commerce.

59. Many of the activities of the HDA and its co-conspirators in administering the wholesale distribution of pharmaceutical products are in the regular, continuous, and substantial flow of interstate commerce, and have a substantial effect on interstate commerce.

60. Many of the conspiratorial and anticompetitive acts alleged herein undertaken by the HDA and its co-conspirators had, and continue to have, a direct, substantial, and reasonably foreseeable impact on interstate commerce.

**B. Relevant Markets**

*1. The DSCSA track-and-trace compliance solutions product market*

61. A relevant product market in this case is the market for DSCSA track-and-trace compliance solutions to companies in the life sciences supply chain.

62. The DSCSA requires manufacturers, repackagers, wholesaler distributors, and retail dispensers to ensure that all prior transaction information is provided and updated at each transfer of ownership of pharmaceutical drugs. Any solution to exchange transaction information needs to be interoperable among many companies in the life sciences supply chain. As a result, the relevant product market consists of data management and exchange services that enable the product's customers to exchange standardized data regarding pharmaceutical supplies as they flow through the supply chain.

63. Except to the extent that competition has been restrained as alleged in this Complaint, TraceLink, and other providers of DSCSA track-and-trace compliance solutions, compete directly with the HDA's Origin product.

64. The market for DSCSA track-and-trace compliance services is two-sided and is thus characterized by substantial network effects. A particular compliance solution becomes more valuable to life science supply chain businesses as more of its business partners use that product. By mandating the use of Origin and prohibiting the extraction of data from Origin into competing compliance solutions, the HDA and its co-conspirators have caused competitive track and trace product suppliers, such as TraceLink, to incur negative network impacts. This occurs because businesses whose trade partners are unable to use the products of these competitive track and trace product suppliers (due to the anticompetitive acts set forth herein) will find these competitive solutions less valuable.

65. As more supply chain partners subscribe to a given compliance solution, they will find it cost-prohibitive to switch to or to use in parallel a competing compliance solution that

does not contain as many users. Accordingly, the more these partners are forced to subscribe to Origin, the less likely that it will be that these partners will seek to switch to Origin competitors in the future.

66. The market for track-and-trace compliance solutions is a relevant market because few, if any, economic substitutes exist for purchasers of such services. A hypothetical monopolist of track-and-trace compliance solutions could raise its price in a small, but significant, non-transitory manner.

*2. The life sciences wholesale distribution product market*

67. A relevant product market in this case is the market for the wholesale distribution of life sciences products.

68. The DSCSA requires the Food & Drug Administration to establish standards for the licensing of wholesaler distributors for pharmaceutical products. As a result, companies in the life sciences supply chain must deal with a licensed wholesaler distributor (or, to a far lesser degree, directly with a manufacturer) to secure pharmaceutical products.

69. Along with the delivery of pharmaceuticals, wholesaler distributors have a broad range of value-added services that they can provide to their dispensing customers. These services are often not provided by the manufacturer and it would be difficult and costly for the dispenser to reproduce them. Wholesaler distributors have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock. Wholesalers' inventory management systems help customers minimize inventory and reduce inventory carrying costs while maintaining adequate inventory to meet patients' needs. Wholesalers can combine the purchase volumes of customers and negotiate the cost of goods with manufacturers. Other services available from wholesalers

include marketing and advertising programs, pharmacy networks for managed care plans, and software to assist with manufacturer bidding.

70. Wholesale distribution of pharmaceuticals is a difficult and highly regulated business with many barriers to entry. There are very few, if any, economic substitutes to wholesaler distributors for the purchase of pharmaceutical product. As a result, a hypothetical monopolist of wholesale distribution could therefore raise its price in a small, but significant, non-transitory manner.

71. The Big Three, along with a number of smaller HDA members, compete in the wholesale distribution market.

*3. The relevant geographic market is the United States*

72. The relevant geographic market for the market of track-and-trace compliance solutions and wholesale distribution of life sciences products is the United States.

73. National laws and regulations demonstrate that the United States is the relevant geographic market in this case. For example, the DSCSA creates particular restrictions on companies in the life sciences supply chain from obtaining prescription drugs without information about the history, origin, and transfer of the product. Doing so illegally would pose a serious safety risk, because the DSCSA-required information ensures that the product matches the label. Further, the DSCSA requires companies to make assurances to the FDA that they have complied with the law, or else risk losing their license to participate in the life sciences supply chain. The DSCSA, and other laws and regulations applying to the life sciences industry, do not apply to participants outside of the United States pharmaceutical supply chain.

**C. Market Power**

74. The HDA, individually and jointly with its co-conspirators, has market power in the market for DSCSA track-and-trace compliance solutions. As described in paragraphs 23-55, *supra*, the HDA has the ability to exclude—and has already excluded—competition in these markets by virtue of its members' market power of wholesale distribution.

75. The HDA serves as the conspiratorial conduit for the collective actions of its members, who conspire through meetings held through the HDA and otherwise, including meetings of the HDA Board of Directors, Executive Committee, and workgroups, such as the Traceability Workgroup. Notably, executives from each of the Big Three serve on the HDA Board of Directors, Executive Committee and Traceability Workgroup, and have participated in meetings and discussions held by these HDA groups. Moreover, the HDA's supply of a track and trace compliance product constitutes the collective actions of its members, as those members will benefit from the financial and other rewards that are provided through this commercial activity.

76. As a result, the HDA's power in the track-and-trace compliance solution market emanates from the market power that its members, particularly the Big Three, wield in the wholesale distribution market. Virtually all businesses in the life sciences supply chain, such as dispensers, manufacturers, or third-party service providers, deal with HDA members, particularly the Big Three, for wholesale distribution. The collective share of the Big Three alone in these markets exceeds 80%.

77. Members of the HDA have exercised their individual and collective market power to force customers to use Origin, despite their customers' desire to use superior open standards-based track and trace compliance solutions, such as that offered by TraceLink.

**D. Harm to Competition**

78. The HDA's anticompetitive conduct has harmed and will continue to harm competition in the DSCSA track-and-trace compliance solution market, including competition from TraceLink, by precluding interoperability and significantly reducing the quality of compliance services on which companies can rely. The HDA's anticompetitive conduct has already caused, and likely will cause, a significant increase in the price for DSCSA track-and-trace compliance solutions. The HDA's illegal conduct has prevented and will likely continue to prevent life sciences companies from obtaining the benefit of competitive compliance services.

79. With respect to TraceLink specifically, the HDA's actions have deprived and will continue to deprive TraceLink's customers of a superior product that, among other things, tracks more specific transactional information and has greater ease of use. TraceLink provides tailor-made solutions for regulatory requirements in countries around the world, including the United States, China, Brazil, India, South Korea, the European Union, and more. Origin does not. As a result, TraceLink's compliance solutions lead to better and more efficient regulatory compliance and lower compliance costs for companies in the life sciences supply chain. The HDA's conduct is intended to force and will have the effect of forcing companies who subscribe to TraceLink's compliance solutions to transfer their business for track and trace master data solutions to the HDA's own proprietary Origin product.

## TORT ALLEGATIONS

80. The HDA has tortiously interfered with the contractual relationships between TraceLink and its customers in violation of Virginia common law. The HDA knew of these contractual relationships and TraceLink's expectancy to earn profits therefrom. TraceLink has suffered damage as a result of HDA's unlawful actions.

81. The HDA has tortiously interfered with TraceLink's prospective business relations in violation of Virginia common law. The HDA knew of TraceLink's prospective business relations, particularly with those business entities that would have considered TraceLink as an option for a master data solution but for the conduct of the HDA, and absent the HDA's conduct, TraceLink would have realized this expectancy. The HDA used improper means to intentionally interfere with TraceLink's prospective business relations, and TraceLink has suffered damage as a result.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

### (*Per Se* or Rule of Reason Group Boycott in the Market for DSCSA Track-and-Trace Compliance Services in Violation of Sherman Act § 1)

82. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

83. The HDA, along with its co-conspirators, has entered into continuing illegal contracts, combinations, or conspiracies in restraint of trade, the purpose and effect of which are to eliminate competition from service providers providing certain DSCSA track-and-trace compliance solutions in the United States.

84. These contracts, combinations, agreements, or conspiracies are illegal both *per se* and under the Rule of Reason under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

85. The HDA possesses and exercises market power in the market for DSCSA track-and-trace compliance solutions. This market power emanates from the market power in the wholesale distribution market for pharmaceutical products wielded by the HDA's members, particularly the Big Three wholesaler distributors.

86. These contracts, combinations, agreements, or conspiracies have caused substantial anticompetitive effects.

87. These contracts, combinations, agreements, or conspiracies have excluded competition from service providers providing certain DSCSA track-and-trace compliance solutions, have reduced the quality of compliance services available to businesses in the life sciences supply chain, and have caused, or will likely cause, an increase in price of compliance services to businesses.

88. These contracts, combinations, agreements, or conspiracies have no legitimate business purpose or offsetting procompetitive impact.

89. These contracts, combinations, agreements, or conspiracies have no legitimate data security purpose or offsetting procompetitive compact.

90. TraceLink has suffered and will continue to suffer injury as a direct result of the HDA's conspiratorial actions. TraceLink has been forced to discontinue certain product sales to a substantial portion of its customer base due to the HDA conspiracy. TraceLink has suffered antitrust injury from HDA's conspiratorial acts.

91. As a result of these violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, TraceLink has been injured in its business and property in an amount not presently known.

## SECOND CLAIM FOR RELIEF

### (Conspiracy to Monopolize the Market for DSCSA Track-and-Trace Compliance Services in Violation of Sherman Act § 2)

92. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

93. The HDA's and its co-conspirators' conduct in foreclosing competition in the DSCSA track-and-trace compliance services market constitutes a conspiracy to monopolize that market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

94. To foreclose competition in the DSCSA track-and-trace compliance services market, the HDA and its co-conspirators have coordinated their efforts to develop a proprietary compliance solution, Origin, and to force businesses in the life sciences supply chain to use Origin as their exclusive service. The HDA and its co-conspirators have willfully, knowingly, and with specific intent, combined or conspired to monopolize the DSCSA track-and-trace compliance services market.

95. If the HDA's exclusionary conduct is not enjoined, there is a dangerous likelihood that defendant will monopolize the market for those certain DSCSA track-and-trace compliance services.

96. The HDA's exclusion of TraceLink has substantial anticompetitive effects. The HDA's illegal conduct will prevent the thousands of businesses in the life sciences supply chain from obtaining the benefit of TraceLink's Life Sciences Cloud's expertise and transnational integration, as well as TraceLink's exceptional customer service and ease of use. It will also result, or has resulted already, in an increase in cost to businesses of complying with the DSCSA.

97. There is no legitimate business purpose or offsetting procompetitive impact resulting from the foreclosure of competition caused by the HDA.

98. TraceLink has suffered and will continue to suffer injury as a direct and proximate result of the HDA's exclusionary conduct. TraceLink has been forced to discontinue certain product sales to a substantial portion of its customer base due to HDA's exclusionary conduct. TraceLink has suffered antitrust injury from the HDA's acts of monopolization.

99. As a result of these violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, TraceLink has been injured in its business and property in an amount not presently known.

**THIRD CLAIM FOR RELIEF**

**(*Per Se* or Rule of Reason Group Boycott in the Market for DSCSA Track-and-Trace Compliance Services in Violation of the Virginia Antitrust Act § 59.1-9.5)**

100. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

101. The HDA, along with its co-conspirators, has entered into continuing illegal contracts, combinations, or conspiracies in restraint of trade, the purpose and effect of which are to eliminate competition from service providers providing certain DSCSA track-and-trace compliance solutions in the United States.

102. These contracts, combinations, agreements, or conspiracies are illegal both *per se* and under the Rule of Reason under the Virginia Antitrust Act, Va. Code § 59.1-9.5 and § 59.1-9.12.

103. The HDA possesses and exercises market power in the market for DSCSA track-and-trace compliance solutions. This market power emanates from the market power in the wholesale distribution market for pharmaceutical products wielded by the HDA's members, particularly the Big Three wholesaler distributors.

104. These contracts, combinations, agreements, or conspiracies have caused substantial anticompetitive effects.

105. These contracts, combinations, agreements, or conspiracies have excluded competition from service providers providing DSCSA track-and-trace compliance solutions, have reduced the quality of compliance services available to businesses in the life sciences

supply chain, and have caused or will likely cause an increase in price of compliance services to businesses.

106. These contracts, combinations, agreements, or conspiracies have no legitimate business purpose or offsetting procompetitive impact.

107. TraceLink has suffered and will continue to suffer injury as a direct result of the HDA's conspiratorial actions. TraceLink has been forced to discontinue certain product sales to a substantial portion of its customer base due to the HDA conspiracy. TraceLink has suffered antitrust injury from HDA's conspiratorial acts.

108. As a result of these violations of the Virginia Antitrust Act, Va. Code § 59.1-9.5 and § 59.1-9.12, TraceLink has been injured in its business and property in an amount not presently known.

**FOURTH CLAIM FOR RELIEF**

**(Conspiracy to Monopolize the Market for DSCSA Track-and-Trace Compliance Services in Violation of the Virginia Antitrust Act § 59.1-9.6)**

109. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

110. The HDA's and its co-conspirators' conduct in foreclosing competition in the DSCSA track-and-trace compliance services market constitutes a conspiracy to monopolize that market in violation of the Virginia Antitrust Act, Va. Code § 59.1-9.6 and § 59.1-9.12.

111. To foreclose competition in the DSCSA track-and-trace compliance services market, the HDA and its co-conspirators have coordinated their efforts to develop a proprietary compliance solution, Origin, and to force businesses in the life sciences supply chain to use Origin as their exclusive compliance service for master data. The HDA and its co-conspirators

have willfully, knowingly, and with specific intent to do so, combined or conspired to monopolize the DSCSA track-and-trace compliance services market.

112. The HDA's exclusion of TraceLink has substantial anticompetitive effects. The HDA's illegal conduct will prevent the thousands of businesses in the life sciences supply chain from obtaining the benefit of TraceLink's Life Sciences Cloud's expertise and transnational integration, as well as TraceLink's exceptional customer service and ease of use. It will also result, or has resulted already, in an increase in cost to businesses of complying with the DSCSA.

113. If the HDA's exclusionary conduct is not enjoined, there is a dangerous likelihood that defendant will monopolize the market for DSCSA track-and-trace compliance services.

114. There is no legitimate business purpose or offsetting procompetitive impact resulting from the foreclosure of competition caused by the HDA.

115. TraceLink has suffered and will continue to suffer injury as a direct and proximate result of the HDA's exclusionary conduct. TraceLink has been forced to discontinue certain product sales to a substantial portion of its customer base due to HDA's exclusionary conduct. TraceLink has suffered antitrust injury from the HDA's acts of monopolization.

116. The HDA's unlawful acquisition and maintenance of monopoly power constitutes a violation of the Virginia Antitrust Act, Va. Code § 59.1-9.6 and § 59.1-9.12.

117. As a result of these violations of the Virginia Antitrust Act, Va. Code § 59.1-9.5 and § 59.1-9.12, TraceLink has been injured in its business and property in an amount not presently known.

**FIFTH CLAIM FOR RELIEF**

**(Tortious Interference with Contract)**

118. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

119. TraceLink has a contractual relationship with each business who subscribes to its DSCSA track-and-trace compliance solution. The HDA knew of these contractual relationships.

120. The HDA intentionally sought to disrupt the contractual relationship between TraceLink and its customers by forcing them to exclusively use Origin for a DSCSA track-and-trace compliance solution.

121. As a direct and proximate result of the HDA's conduct, a number of TraceLink's customers have cancelled their subscriptions for TraceLink's Life Sciences Cloud, or have otherwise suspended or terminated their relationship with TraceLink.

122. TraceLink has been damaged by this disruption of the contractual relationships with its customers, in an amount to be proven at trial.

**SIXTH CLAIM FOR RELIEF**

**(Tortious Interference with Prospective Business Relations)**

123. TraceLink repeats and realleges each and every allegation of this Complaint as if fully set forth herein.

124. TraceLink has an expectancy of contractual relationship with each business who may choose to subscribe to its DSCSA track-and-trace compliance solution. The HDA knew of these expected business relations.

125. The HDA intentionally sought to disrupt these expected business relations between TraceLink and its customers and potential customers, by forcing them to exclusively use Origin as a DSCSA track-and-trace compliance solution.

126. As a direct and proximate result of the HDA's conduct, a number of TraceLink's customers have cancelled their subscriptions for TraceLink's Life Sciences Cloud, or have otherwise suspended or terminated their relationship with TraceLink. Thus there exists a reasonable certainty that absent the HDA's improper and intentional conduct, TraceLink would have realized the expectancy of additional business relations.

127. TraceLink has been damaged by this disruption of the contractual relationships with its customers, in an amount to be proven at trial.

## DEMAND FOR RELIEF

**WHEREFORE**, TraceLink respectfully demands:

A. that the Court declare, adjudge, and decree that Defendant has committed the violations of law alleged herein;

B. that the Court award damages sustained by TraceLink because of Defendant's misconduct, in an amount to be proved at trial, to be trebled in accordance with antitrust law, plus interest, including prejudgment interest, attorneys' fees, and costs of suit;

C. that the Court enjoin Defendant from requiring—either directly or indirectly through its wholesaler distributor members—that entities use the Origin product;

D. that the Court enjoin Defendant from including the non-compete clauses from Origin-related Agreements, including without limitation § 5(g) and (h) of the Origin User Agreement, and § 8(f) and (g) of the Origin Contributor Agreement; and

E. that the Court grant such other and further relief as it may deem just and proper.

**JURY DEMAND**

TraceLink hereby demands trial by jury of all issues properly triable thereby.

October 23, 2017

By: _____/s/_____

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**Pro hac vice* motion to follow